

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

<p>IN RE: PLAVIX PRODUCT LIABILITY AND MARKETING LITIGATION</p>	MDL No. 3:13-cv-02418-FLW-TJB
<p>This Document Relates to: RHONDA GRISHAM, individually and as Personal Representative of the Estate of Jed Grisham, Deceased, Plaintiffs, v. BRISTOL-MYERS SQUIBB COMPANY, SANOFI-AVENTIS U.S., L.L.C., SANOFI US SERVICES INC. f/k/a SANOFI-AVENTIS, U.S., INC., and SANOFI-SYNTHELABO, INC. Defendants.</p>	Case No. 3:13-cv-03775-FLW-TJB

DEFENDANTS' ANSWER TO COMPLAINT AND JURY DEMAND

ARNOLD & PORTER LLP
555 Twelfth Street N.W.
Washington, D.C. 20004
Telephone No. (202) 942-5000
Fax No. (202) 942-5999

LOWENSTEIN SANDLER LLP
65 Livingston Avenue
Roseland, N.J. 07068
Tel. No. (973) 597-2500
Fax No. (973) 597-2379

Attorneys for Defendants Bristol-Myers Squibb Company, Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., and Sanofi-Synthelabo Inc.

Defendants Bristol-Myers Squibb Company (“BMS”), Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., and Sanofi-Synthelabo Inc.¹ (collectively, “Defendants”), by and through undersigned counsel, hereby answer Plaintiff’s Complaint (the “Complaint”).

Plaintiff’s Complaint consists largely of sweeping, conclusory allegations about Defendants’ conduct without factual allegations supporting those averments. The Complaint also fails to connect the few factual allegations that are made with Plaintiff’s decedent’s Plavix® prescription or alleged injuries, and fails to show how those factual allegations relate to or support the vague legal claims asserted. Accordingly, Defendants offer their responses herein without prejudice to their right to seek relief from the Court based on Plaintiff’s failure to state a claim upon which relief can be granted and/or Plaintiff’s failure to satisfy applicable pleading standards.

Plaintiff’s Complaint also includes unnumbered paragraphs beginning “Wherefore” following each of the paragraphs numbered 84, 89, 99, and 111. These “Wherefore” paragraphs contain only legal conclusions and descriptions of the relief sought in Plaintiff’s Complaint to which no response is necessary. To the extent a response is deemed necessary, Defendants deny the allegations in each and every one of the aforementioned “Wherefore” paragraphs and deny that Defendants are liable to Plaintiff in any way whatsoever.

As to each allegation, Defendants respond as follows. All allegations are denied unless specifically admitted.

¹ Sanofi-Aventis U.S. LLC was incorrectly designated “Sanofi-Aventis U.S. L.L.C.” and Sanofi-Synthelabo Inc. was incorrectly designated “Sanofi-Synthelabo, Inc.” in the Complaint. Sanofi-Aventis U.S. Inc., incorrectly designated as “Sanofi-Aventis U.S., Inc.” in the Complaint, changed its name to Sanofi US Services Inc. in June 2012.

PARTIES

1. To the extent Paragraph 1 alleges the residence of Plaintiff, Defendants lack knowledge or information sufficient to form a belief as to the allegations and therefore deny the same. To the extent the allegations of Paragraph 1 are intended to summarize allegations set forth in Plaintiff's Complaint, the allegations are improper and require. To the extent a response is deemed necessary, Defendants admit that Plaintiff brings this action but deny that Plaintiff is entitled to any relief against Defendants whatsoever. Defendants deny the remaining allegations in Paragraph 1.

2. Answering the allegations of Paragraph 2, Defendants state that BMS is a Delaware pharmaceutical company that maintains its headquarters at 345 Park Avenue, New York, New York 10154. Defendants further state that the Bristol-Myers Squibb/Sanofi Pharmaceuticals Partnership has been responsible for manufacturing and marketing Plavix® in, among other places, the United States. Defendants deny the remaining allegations of Paragraph 2.

3. Answering the allegations of Paragraph 3, Defendants state that Sanofi-Aventis U.S. LLC is a Delaware limited liability company that maintains its headquarters at 55 Corporate Drive, Bridgewater, New Jersey 08807. Defendants further state that Sanofi-Aventis U.S. LLC is a wholly owned indirect subsidiary of the French pharmaceutical company Sanofi.² Defendants further state that the Bristol-Myers Squibb/Sanofi Pharmaceuticals Partnership has been responsible for manufacturing and marketing Plavix® in, among other places, the United

² As of May 6, 2011, the French pharmaceutical company Sanofi-Aventis shortened its name to Sanofi.

States. Defendants deny the remaining allegations of Paragraph 3.

4. Answering the allegations of Paragraph 4, Defendants state that Sanofi US Services Inc. (f/k/a Sanofi-Aventis U.S. Inc.) is a Delaware corporation that maintains its headquarters at 55 Corporate Drive, Bridgewater, New Jersey 08807. Defendants further state that Sanofi US Services Inc. is a wholly owned indirect subsidiary of the French pharmaceutical company Sanofi. Defendants further state that the Bristol-Myers Squibb/Sanofi Pharmaceuticals Partnership has been responsible for manufacturing and marketing Plavix® in, among other places, the United States. Defendants deny the remaining allegations of Paragraph 4.

5. Answering the allegations of Paragraph 5, Defendants state that Sanofi-Synthelabo Inc. is a Delaware corporation that maintained its headquarters at 90 Park Avenue, New York, New York 10016 until May 2005, at which time it moved to New Jersey, and that Sanofi-Synthelabo Inc. is affiliated with Sanofi-Aventis U.S. LLC and Sanofi US Services Inc. Defendants further state that Sanofi-Synthelabo Inc. previously did business as Sanofi Pharmaceuticals, Inc., and that, until the creation of Sanofi-Aventis U.S. LLC, Sanofi-Synthelabo Inc. was the holder of the Plavix® New Drug Application (the “NDA”). Defendants deny the remaining allegations of Paragraph 5.

6. The allegations in Paragraph 6 require no response.

JURISDICTION AND VENUE

7. The allegations in Paragraph 7 assert a legal conclusion to which no response is required. To the extent a response is deemed necessary, Defendants deny the same.

8. The allegations in Paragraph 8 assert a legal conclusion to which no response is required. To the extent a response is deemed necessary, Defendants deny the same.

9. The allegations in Paragraph 9 assert a legal conclusion to which no response is required. To the extent a response is deemed necessary, Defendants deny the same.

STATEMENT OF FACTS

Answering the unnumbered paragraph following Paragraph 9, Defendants state that they lack knowledge or information sufficient to form a belief as to the allegations and therefore deny the same.

10. To the extent the allegations of Paragraph 10 are intended to summarize allegations set forth in Plaintiff's Complaint, the allegations are improper and require no response. To the extent a response is deemed necessary, Defendants deny the same.

11. Answering the allegations of Paragraph 11, Defendants state that the Bristol-Myers Squibb/Sanofi Pharmaceuticals Partnership has been responsible for manufacturing, testing, promoting, marketing, distributing, labeling, and selling the prescription drug Plavix® in, among other places, the United States. Defendants deny the remaining allegations in Paragraph 11.

12. Answering the allegations of Paragraph 12, Defendants state that in April 1997 the U.S. Food and Drug Administration ("FDA") granted the Plavix® NDA a priority review and that on November 17, 1997, after completing this review, FDA determined that Plavix® was safe and effective for use in accordance with its FDA-approved label, and approved Plavix® for sale in the United States. Defendants further state that in March 1998, a few months after Plavix® was approved by FDA, the Bristol-Myers Squibb/Sanofi Pharmaceuticals Partnership began to market and sell Plavix® in the United States. Defendants deny the remaining allegations in Paragraph 12.

13. Defendants deny the allegations in Paragraph 13.

14. Answering the allegations of Paragraph 14, Defendants state that Plavix® has been marketed through television, magazine, and Internet advertisements to both medical professionals and consumers. Defendants further state that the Plavix® marketing material content speaks for itself. Defendants deny the remaining allegations in Paragraph 14.

15. Defendants deny the allegations in Paragraph 15.

16. Defendants deny the allegations in Paragraph 16.

17. Answering the allegations of Paragraph 17, Defendants state that global sales of Plavix® exceeded \$3.8 billion in 2005. Defendants deny the remaining allegations in Paragraph 17.

18. Defendants deny the allegations in Paragraph 18.

19. Answering the allegations of Paragraph 19, Defendants state that, in accordance with FDA regulations and applicable standards of care and law, correspondence on behalf of the Bristol-Myers Squibb/Sanofi Pharmaceuticals Partnership was exchanged with FDA addressing the content of certain promotional materials related to Plavix®, and that this correspondence and the content of the marketing materials speak for themselves. To the extent Paragraph 19 alleges any wrongdoing or wrongful acts by Defendants or alleges that Defendants are liable to Plaintiff or that Plaintiff is entitled to any relief in this action, Defendants deny the same. Defendants deny the remaining allegations in Paragraph 19.

20. Answering the allegations of Paragraph 20, Defendants state that, in accordance with FDA regulations and applicable standards of care and law, correspondence on behalf of the Bristol-Myers Squibb/Sanofi Pharmaceuticals Partnership was exchanged with FDA addressing the content of certain promotional materials related to Plavix®, and that this correspondence and the content of the marketing materials speak for themselves. Defendants further state that

the CHARISMA (Clopidogrel and Aspirin Versus Aspirin Alone for the Prevention of Atherothrombotic Events) Study was conducted and reported in The New England Journal of Medicine on April 20, 2006, and that this study and its results speak for themselves. To the extent Paragraph 20 alleges any wrongdoing or wrongful acts by Defendants or alleges that Defendants are liable to Plaintiff or that Plaintiff is entitled to any relief in this action, Defendants deny the same. Defendants deny the remaining allegations in Paragraph 20.

21. Answering the allegations of Paragraph 21, Defendants state that, in accordance with FDA regulations and applicable standards of care and law, correspondence on behalf of the Bristol-Myers Squibb/Sanofi Pharmaceuticals Partnership was exchanged with FDA addressing the content of certain promotional materials related to Plavix®, and that this correspondence and the content of the marketing materials speak for themselves. To the extent Paragraph 21 alleges any wrongdoing or wrongful acts by Defendants or alleges that Defendants are liable to Plaintiff or that Plaintiff is entitled to any relief in this action, Defendants deny the same. Defendants deny the remaining allegations in Paragraph 21.

22. Answering the allegations of Paragraph 22, Defendants state that, in accordance with FDA regulations and applicable standards of care and law, correspondence on behalf of the Bristol-Myers Squibb/Sanofi Pharmaceuticals Partnership was exchanged with FDA addressing the content of certain promotional materials related to Plavix®, and that this correspondence and the content of the marketing materials speak for themselves. Defendants further state that the CAPRIE (Clopidogrel Versus Aspirin in Patients at Risk of Ischemic Events) Study was conducted and reported in The Lancet, and that this study and its results speak for themselves. To the extent Paragraph 22 alleges any wrongdoing or wrongful acts by Defendants or alleges that Defendants are liable to Plaintiff or that Plaintiff is entitled to any relief in this action,

Defendants deny the same. Defendants deny the remaining allegations in Paragraph 22.

23. Defendants deny the allegations in Paragraph 23.
24. Defendants deny the allegations in Paragraph 24.
25. Defendants deny the allegations in Paragraph 25.
26. Defendants deny the allegations in Paragraph 26.
27. Defendants deny the allegations in Paragraph 27.
28. Defendants deny the allegations in Paragraph 28.
29. Defendants deny the allegations in Paragraph 29.
30. Defendants deny the allegations in Paragraph 30.
31. Answering the allegations of Paragraph 31, Defendants state that the “Chan Study” was conducted and reported in The New England Journal of Medicine, and that this study and its results speak for themselves. Defendants deny the remaining allegations in Paragraph 31.
32. Answering the allegations of Paragraph 32, Defendants state that the “Chan Study” was conducted and reported in The New England Journal of Medicine, and that this study and its results speak for themselves. Defendants deny the remaining allegations in Paragraph 32.
33. Answering the allegations of Paragraph 33, Defendants state that the CHARISMA (Clopidogrel and Aspirin Versus Aspirin Alone for the Prevention of Atherothrombotic Events) Study was conducted and reported in The New England Journal of Medicine, and that this study and its results speak for themselves. Defendants deny the remaining allegations in Paragraph 33.
34. Defendants deny the allegations in Paragraph 34.

35. Answering the allegations of Paragraph 35, Defendants state that FDA has approved the Plavix® labeling accompanying the product and that the Plavix® label is published in the Physician's Desk Reference. Defendants deny the remaining allegations in Paragraph 35.

36. Answering the allegations of Paragraph 36, Defendants state that the legal duties concerning prescription drug labeling are governed by applicable laws and regulations. Defendants deny the remaining allegations in Paragraph 36.

37. Defendants deny the allegations in Paragraph 37.

38. Defendants deny the allegations in Paragraph 38.

39. Defendants deny the allegations in Paragraph 39.

40. Defendants deny the allegations in Paragraph 40.

41. Answering the allegations of Paragraph 41, Defendants state that the legal duties concerning the reporting of information to FDA and the Plavix® label are governed by applicable laws and regulations. Defendants deny the remaining allegations in Paragraph 41.

42. To the extent the allegations of Paragraph 42 attempt to set forth a legal duty, the allegations call for a legal conclusion to which no response is required. To the extent a response is deemed necessary, Defendants state that the legal duties concerning the Plavix® label are governed by applicable laws and regulations. Defendants deny the remaining allegations in Paragraph 42.

43. Defendants deny the allegations in Paragraph 43.

44. To the extent the allegations of Paragraph 44 attempt to set forth a legal duty, the allegations call for a legal conclusion to which no response is required. To the extent a response is deemed necessary, Defendants state that the legal duties concerning post-marketing

safety surveillance are governed by applicable laws and regulations. Defendants deny the remaining allegations in Paragraph 44.

45. Defendants deny the allegations in Paragraph 45.

46. Defendants deny the allegations in Paragraph 46.

47. Defendants deny the allegations in Paragraph 47.

48. Defendants deny the allegations in Paragraph 48.

49. Defendants deny the allegations in Paragraph 49.

50. Defendants deny the allegations in Paragraph 50.

51. Defendants deny the allegations in Paragraph 51.

52. To the extent Paragraph 52 alleges that Plaintiff suffered any injuries, losses, or damages, Defendants lack knowledge or information sufficient to form a belief as to the allegations and therefore deny the same. To the extent Paragraph 52 alleges any wrongdoing or wrongful acts by Defendants or alleges that Defendants are liable to Plaintiff or that Plaintiff is entitled to any damages from Defendants, Defendants deny the same. Defendants deny the remaining allegations in Paragraph 52.

53. Defendants deny the allegations in Paragraph 53.

54. To the extent Paragraph 54 alleges that Plaintiff suffered any injuries, losses, or damages, Defendants lack knowledge or information sufficient to form a belief as to the allegations and therefore deny the same. To the extent Paragraph 54 alleges any wrongdoing or wrongful acts by Defendants or alleges that Defendants are liable to Plaintiff or that Plaintiff is entitled to any damages from Defendants, Defendants deny the same. Defendants deny the remaining allegations in Paragraph 54.

55. To the extent the allegations of Paragraph 55 attempt to set forth a legal duty, the

allegations call for a legal conclusion to which no response is required. To the extent a response is deemed necessary, Defendants state that their legal duties are governed by applicable laws and regulations. Defendants deny the remaining allegations in Paragraph 55.

56. To the extent the allegations of Paragraph 56 attempt to set forth a legal duty, the allegations call for a legal conclusion to which no response is required. To the extent a response is deemed necessary, Defendants state that their legal duties are governed by applicable laws and regulations. Defendants deny the remaining allegations in Paragraph 56.

57. To the extent Paragraph 57 alleges that Plaintiff suffered any injuries, losses, or damages, Defendants lack knowledge or information sufficient to form a belief as to the allegations and therefore deny the same. To the extent Paragraph 57 alleges any wrongdoing or wrongful acts by Defendants or alleges that Defendants are liable to Plaintiff or that Plaintiff is entitled to any damages from Defendants, Defendants deny the same. Defendants deny the remaining allegations in Paragraph 57.

58. Defendants deny the allegations in Paragraph 58.

59. Defendants deny the allegations in Paragraph 59.

60. To the extent Paragraph 60 alleges that Plaintiff's physicians acted as ordinary, reasonable, and prudent physicians or that Plaintiff's decedent was an ordinary, reasonable, and prudent patient, Defendants lack knowledge or information sufficient to form a belief as to the allegations and therefore deny the same. Defendants deny the remaining allegations in Paragraph 60.

61. To the extent Paragraph 61, including all subparts thereof, alleges that Plaintiff suffered any injuries, losses, or damages, Defendants lack knowledge or information sufficient to form a belief as to the allegations and therefore deny the same. To the extent Paragraph 61,

including all subparts thereof, alleges any wrongdoing or wrongful acts by Defendants or alleges that Defendants are liable to Plaintiff or that Plaintiff is entitled to any damages from Defendants, Defendants deny the same. Defendants deny the remaining allegations in Paragraph 61, including all subparts thereof.

62. Defendants deny the allegations in Paragraph 62.

63. To the extent Paragraph 63 alleges that Plaintiff suffered any injuries, losses, or damages, Defendants lack knowledge or information sufficient to form a belief as to the allegations and therefore deny the same. To the extent Paragraph 63 alleges any wrongdoing or wrongful acts by Defendants or alleges that Defendants are liable to Plaintiff or that Plaintiff is entitled to any damages from Defendants, Defendants deny the same. Defendants deny the remaining allegations in Paragraph 63.

WRONGFUL CONDUCT

COUNT I **STRICT PRODUCTS LIABILITY**

64. Answering the allegations of Paragraph 64, Defendants state that the Bristol-Myers Squibb/Sanofi Pharmaceuticals Partnership has been responsible for manufacturing, testing, promoting, marketing, distributing, labeling, and selling the prescription drug Plavix® in, among other places, the United States. Defendants deny the remaining allegations in Paragraph 64.

65. Defendants deny the allegations in Paragraph 65.

66. Defendants deny the allegations in Paragraph 66.

67. Defendants deny the allegations in Paragraph 67.

68. Defendants deny the allegations in Paragraph 68.

69. Answering the allegations of Paragraph 69, Defendants state that Plavix® has

been prescribed and sold to consumers throughout the United States. Defendants lack knowledge or information sufficient to form a belief as to the remaining allegations of Paragraph 69 and therefore deny the same.

70. Answering the allegations of Paragraph 70, Defendants state that the Bristol-Myers Squibb/Sanofi Pharmaceuticals Partnership has been responsible for manufacturing, testing, promoting, marketing, distributing, labeling, and selling the prescription drug Plavix® in, among other places, the United States. Defendants deny the remaining allegations in Paragraph 70.

71. Defendants deny the allegations in Paragraph 71.

72. Defendants deny the allegations in Paragraph 72.

73. Defendants deny the allegations in Paragraph 73.

74. Defendants deny the allegations in Paragraph 74.

75. Defendants deny the allegations in Paragraph 75, including all subparts thereof.

76. Defendants deny the allegations in Paragraph 76.

77. Defendants deny the allegations in Paragraph 77.

78. To the extent Paragraph 78 alleges that Plaintiff used Plavix®, Defendants lack knowledge or information sufficient to form a belief as to the allegations and therefore deny the same. Defendants deny the remaining allegations in Paragraph 78.

79. Defendants deny the allegations in Paragraph 79.

80. To the extent Paragraph 80 alleges what Plaintiff or Plaintiff's physicians knew about Plavix®, Defendants lack knowledge or information sufficient to form a belief as to the allegations and therefore deny the same. Defendants deny the remaining allegations in Paragraph 80.

81. To the extent Paragraph 81 alleges that Plaintiff suffered any injuries, losses, or damages, Defendants lack knowledge or information sufficient to form a belief as to the allegations and therefore deny the same. To the extent Paragraph 81 alleges any wrongdoing or wrongful acts by Defendants or alleges that Defendants are liable to Plaintiff or that Plaintiff is entitled to any damages from Defendants, Defendants deny the same. Defendants deny the remaining allegations in Paragraph 81.

82. Defendants deny the allegations in Paragraph 82.

83. To the extent Paragraph 83 alleges that Plaintiff suffered any injuries, losses, or damages, Defendants lack knowledge or information sufficient to form a belief as to the allegations and therefore deny the same. To the extent Paragraph 83 alleges any wrongdoing or wrongful acts by Defendants or alleges that Defendants are liable to Plaintiff or that Plaintiff is entitled to any damages from Defendants, Defendants deny the same. Defendants deny the remaining allegations in Paragraph 83.

84. Defendants deny the allegations in Paragraph 84.

COUNT II
MANUFACTURING DEFECT

85. Answering the allegations of Paragraph 85, Defendants state that the Bristol-Myers Squibb/Sanofi Pharmaceuticals Partnership has been responsible for manufacturing, testing, promoting, marketing, distributing, labeling, and selling the prescription drug Plavix® in, among other places, the United States. Defendants deny the remaining allegations in Paragraph 85.

86. Answering the allegations of Paragraph 86, Defendants state that Plavix® has been prescribed and sold to consumers throughout the United States. Defendants lack knowledge or information sufficient to form a belief as to the remaining allegations of

Paragraph 86 and therefore deny the same.

87. Defendants deny the allegations in Paragraph 87, including all subparts thereof.

88. To the extent Paragraph 88 alleges that Plaintiff suffered any injuries, losses, or damages, Defendants lack knowledge or information sufficient to form a belief as to the allegations and therefore deny the same. To the extent Paragraph 88 alleges any wrongdoing or wrongful acts by Defendants or alleges that Defendants are liable to Plaintiff or that Plaintiff is entitled to any damages from Defendants, Defendants deny the same. Defendants deny the remaining allegations in Paragraph 88.

89. Defendants deny the allegations in Paragraph 89.

COUNT III
FAILURE TO WARN

90. Defendants deny the allegations in Paragraph 90.

91. Defendants deny the allegations in Paragraph 91.

92. Defendants lack knowledge or information sufficient to form a belief as to the allegations of Paragraph 92 and therefore deny the same.

93. To the extent Paragraph 93 alleges what Plaintiff could have known about Plavix®, Defendants lack knowledge or information sufficient to form a belief as to the allegations and therefore deny the same. Defendants deny the remaining allegations in Paragraph 93.

94. Defendants deny the allegations in Paragraph 94.

95. Defendants deny the allegations in Paragraph 95.

96. To the extent Paragraph 96 attempts to set forth upon what Plaintiff or Plaintiff's physicians reasonably relied, Defendants lack knowledge or information sufficient to form a belief as to the allegations and therefore deny the same. To the extent the allegations of

Paragraph 96 attempt to set forth a legal duty, the allegations call for a legal conclusion to which no response is required. To the extent a response is deemed necessary, Defendants deny the same. Defendants deny the remaining allegations in Paragraph 96.

97. To the extent Paragraph 97 alleges that Plaintiff suffered any injuries, losses, or damages, Defendants lack knowledge or information sufficient to form a belief as to the allegations and therefore deny the same. To the extent Paragraph 97 alleges any wrongdoing or wrongful acts by Defendants or alleges that Defendants are liable to Plaintiff or that Plaintiff is entitled to any damages from Defendants, Defendants deny the same. Defendants deny the remaining allegations in Paragraph 97.

98. To the extent Paragraph 98 alleges that Plaintiff suffered any injuries, losses, or damages, Defendants lack knowledge or information sufficient to form a belief as to the allegations and therefore deny the same. To the extent Paragraph 98 alleges any wrongdoing or wrongful acts by Defendants or alleges that Defendants are liable to Plaintiff or that Plaintiff is entitled to any damages from Defendants, Defendants deny the same. Defendants deny the remaining allegations in Paragraph 98.

99. Defendants deny the allegations in Paragraph 99.

COUNT IV
NEGLIGENCE

100. To the extent the allegations of Paragraph 100 attempt to set forth a legal duty, the allegations call for a legal conclusion to which no response is required. To the extent a response is deemed necessary, Defendants deny the same. Defendants deny the remaining allegations in Paragraph 100.

101. To the extent the allegations of Paragraph 101 attempt to set forth a legal duty, the allegations call for a legal conclusion to which no response is required. To the extent a

response is deemed necessary, Defendants deny the same. Defendants deny the remaining allegations in Paragraph 101.

102. Defendants deny the allegations in Paragraph 102.

103. Defendants deny the allegations in Paragraph 103.

104. Defendants deny the allegations in Paragraph 104.

105. Defendants deny the allegations in Paragraph 105.

106. To the extent Paragraph 106 alleges that Plaintiff suffered any injuries, losses, or damages, Defendants lack knowledge or information sufficient to form a belief as to the allegations and therefore deny the same. To the extent Paragraph 106 alleges any wrongdoing or wrongful acts by Defendants or alleges that Defendants are liable to Plaintiff or that Plaintiff is entitled to any damages from Defendants, Defendants deny the same. Defendants deny the remaining allegations in Paragraph 106.

107. Defendants deny the allegations in Paragraph 107, including all subparts thereof

108. To the extent Paragraph 108 alleges that Plaintiff suffered any injuries, losses, or damages, Defendants lack knowledge or information sufficient to form a belief as to the allegations and therefore deny the same. To the extent Paragraph 108 alleges any wrongdoing or wrongful acts by Defendants or alleges that Defendants are liable to Plaintiff or that Plaintiff is entitled to any damages from Defendants, Defendants deny the same. Defendants deny the remaining allegations in Paragraph 108.

109. To the extent Paragraph 109 alleges that Plaintiff suffered any injuries, losses, or damages, Defendants lack knowledge or information sufficient to form a belief as to the allegations and therefore deny the same. To the extent Paragraph 109 alleges any wrongdoing or wrongful acts by Defendants or alleges that Defendants are liable to Plaintiff or that Plaintiff

is entitled to any damages from Defendants, Defendants deny the same. Defendants deny the remaining allegations in Paragraph 109.

110. Defendants deny the allegations in Paragraph 110.

111. Defendants deny the allegations in Paragraph 111.

PRAYER FOR RELIEF

Answering the Paragraph set forth under the heading "Prayer for Relief," Defendants admit that Plaintiff seeks the relief requested but deny that Plaintiff is entitled to any relief against Defendants whatsoever.

AFFIRMATIVE DEFENSES³

FIRST AFFIRMATIVE DEFENSE

Plaintiff's Complaint fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

Plavix® (clopidogrel bisulfate) is, and was at all times, safe for its intended use and not defective or unreasonably dangerous.

THIRD AFFIRMATIVE DEFENSE

Without admitting that the product at issue was manufactured and/or sold by Defendants, to the extent Defendants had any duty with respect to the sale and/or manufacture of the product, such duty was fully discharged by the giving of adequate instructions and warnings concerning its use.

³ Defendants assert the following affirmative defenses without admitting or conceding that all of the affirmative defenses listed below are affirmative defenses for which they carry the burden of proof.

FOURTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part by the principles of the learned intermediary and/or sophisticated user doctrine.

FIFTH AFFIRMATIVE DEFENSE

Plaintiff's alleged injuries and/or medical expenses resulted from pre-existing or unrelated medical, psychiatric, genetic, or environmental conditions, diseases, or illnesses.

SIXTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, by the doctrine of federal preemption.

SEVENTH AFFIRMATIVE DEFENSE

If Plaintiff suffered injuries and damages by reason of operation of nature or idiosyncratic and/or allergic reaction to the product, used either alone or in combination with any other drug, Defendants are not liable.

EIGHTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred or reduced under the principles of assumption of the risk and/or informed consent.

NINTH AFFIRMATIVE DEFENSE

Plaintiff's recovery, if any, from Defendants should be reduced, offset, or barred by the contributory or comparative negligence, fault, responsibility, or causation attributable to Plaintiff or to some third party other than Defendants.

TENTH AFFIRMATIVE DEFENSE

Plaintiff's injuries and damages, if any, were caused in whole or in part by an alteration, change, unintended use, or misuse of the product at issue.

ELEVENTH AFFIRMATIVE DEFENSE

Plaintiff's alleged injuries were caused or contributed to be caused by the intervening acts, superseding negligence, and/or subsequent conduct or fault on the part of a person or entity

over whom Defendants neither had control nor right of control and, therefore, Plaintiff's claims are barred and/or Defendants are entitled to an apportionment of damages accordingly.

TWELFTH AFFIRMATIVE DEFENSE

Plaintiff's alleged damages were not proximately caused by any act or omission of Defendants and/or were caused or proximately caused by some person or third party other than Defendants for whom Defendants are not legally responsible.

THIRTEENTH AFFIRMATIVE DEFENSE

One or more of the claims set forth in Plaintiff's Complaint are barred in whole or in part by the applicable statutes of limitation and/or statutes of repose.

FOURTEENTH AFFIRMATIVE DEFENSE

The product at issue was available only through licensed physicians who were provided complete and adequate warnings and instructions consistent with the state of medical and scientific knowledge at the time.

FIFTEENTH AFFIRMATIVE DEFENSE

Defendants specifically plead collateral estoppel, res judicata, waiver, laches, and failure to mitigate or minimize damages, if any.

SIXTEENTH AFFIRMATIVE DEFENSE

Any acts performed by Defendants in the design, manufacture, and marketing of the product at issue were in conformity with the "state of the art" existing at the time of such design, manufacture, and marketing, and public policy should hold that liability not be imposed on Defendants for untold risks not known at the time of design, manufacture, and marketing of the product at issue.

SEVENTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims should be dismissed due to improper venue and/or pursuant to the doctrine of *forum non conveniens*.

EIGHTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are subject to the limitations set forth in the Restatement (Second) of Torts, section 402A, comment k, and/or the Restatement (Third) of Torts.

NINETEENTH AFFIRMATIVE DEFENSE

Defendants had no duty to warn of the possible dangers of using the product at issue, the existence of which are denied, that were not known at the time of manufacture or sale of the product.

TWENTIETH AFFIRMATIVE DEFENSE

All of Defendants' activities and conduct conformed to all state and federal statutes, regulations, and industry standards based upon the state of knowledge existing at the relevant time.

TWENTY-FIRST AFFIRMATIVE DEFENSE

The methods, standards, and techniques utilized by Defendants in designing, formulating, manufacturing, and marketing the product at issue and in issuing warnings and instructions with respect to its use were proper and in conformity with the generally recognized, reasonably available, and reliable state of knowledge in the field at the time the product was manufactured.

TWENTY-SECOND AFFIRMATIVE DEFENSE

The injuries and/or damages claimed by Plaintiff were the result of unavoidable circumstances that Defendants could not have prevented.

TWENTY-THIRD AFFIRMATIVE DEFENSE

The injuries and/or damages claimed by Plaintiff were the result of a pre-existing condition unrelated to any conduct of, or products placed in the stream of commerce by, Defendants.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

The conduct of Defendants in all activities with respect to the product at issue has been and is under the supervision of FDA. Accordingly, this action is barred by the doctrine of primary jurisdiction.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

The alleged negligent or culpable conduct of Defendants, none being admitted, was so insubstantial as to be insufficient to be a proximate or substantial contributing cause of Plaintiff's alleged injuries.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

The injuries and/or damages claimed by Plaintiff can be attributed to several causes and, accordingly, should be apportioned among the various causes according to the respective contribution of each such cause to the harm sustained.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred because the use of the product at issue was generally recognized as safe and effective pursuant to conditions established by FDA and applicable regulations, including packaging and labeling regulations.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

The public interest, benefit, and availability of the product at issue outweigh the risks, if any, resulting from such activities, which were unavoidable given the state of knowledge at the time those activities were undertaken.

TWENTY-NINTH AFFIRMATIVE DEFENSE

Any verdict or judgment rendered against Defendants must be reduced by those amounts that have or will, with reasonable certainty, replace or indemnify Plaintiff, in whole or in part, for any past or future claimed economic loss, from any collateral source such as insurance, Social Security, worker's compensation, or employee benefit programs.

THIRTIETH AFFIRMATIVE DEFENSE

At the time the product left Defendants' control, there was not a practical and technically feasible alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of the product.

THIRTY-FIRST AFFIRMATIVE DEFENSE

Defendants are not liable for any harm caused because the product at issue contained an adequate warning as evidenced by its approval by FDA under the Federal Food, Drug, and Cosmetic Act.

THIRTY-SECOND AFFIRMATIVE DEFENSE

To the extent Plaintiff seeks equitable relief, such claims are barred because Plaintiff has an adequate remedy at law.

THIRTY-THIRD AFFIRMATIVE DEFENSE

None of the Defendants' acts, conducts, omissions, or statements alleged in the Complaint was likely to mislead.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, because Plaintiff and/or Plaintiff's prescribing physicians knew, at all times, the characteristics, uses, benefits, standard, and quality of the product at issue and therefore could not have justifiably relied on the alleged misrepresentations or omissions in the Complaint.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiff is not entitled to relief under the statutes and legal theories invoked in their Complaint because Plaintiff lacks standing.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

Defendants have fully performed any and all contractual, statutory, and other duties, and Plaintiff is therefore estopped from asserting any cause of action against Defendants.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

Any award to Plaintiff in this action would constitute unjust enrichment.

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

The Complaint and each cause of action therein presented are vague, ambiguous, and uncertain. Defendants reserve the right to add additional defenses as the factual bases for each of Plaintiff's claims and allegations become known.

THIRTY-NINTH AFFIRMATIVE DEFENSE

To the extent permitted by agreement of the parties, Defendant asserts that Plaintiff's Complaint is time-barred due to Plaintiff's failure to timely bring this suit in the jurisdiction required pursuant to that agreement.

FORTIETH AFFIRMATIVE DEFENSE

Defendants rely upon all defenses contained in any applicable state statute or law.

FORTY-FIRST AFFIRMATIVE DEFENSE

Defendants hereby give notice that they intend to rely upon any other defense that may become available or appear during the discovery proceedings in the case and hereby reserve the right to amend this Answer to assert any such defense. Defendants also reserve the right to assert other and related defenses as may become available upon a determination of the law applicable to the action or any part thereof or claim therein.

JURY DEMAND

Defendants hereby demand a jury trial on all issues so triable.

WHEREFORE, Defendants, having fully answered Plaintiff's Complaint, pray that Plaintiff take nothing by this suit and demand as follows:

1. That Plaintiff's Complaint be dismissed with prejudice on the merits;
2. That Defendants recover their costs and disbursements herein expended to the extent permitted under applicable law;
3. That Defendants be granted leave to file an amended pleading upon conclusion of reasonable discovery, if necessary; and
4. That Defendants be granted a jury trial and all other relief to which they are justly entitled.

Respectfully submitted,

/s/ David L. Harris
David L. Harris
Rebecca B. Visvader
LOWENSTEIN SANDLER LLP
65 Livingston Avenue
Roseland, New Jersey 07068
973-597-2378 (Phone)
973-597-2379 (Fax)

Daniel S. Pariser
ARNOLD & PORTER LLP
555 Twelfth Street, N.W.
Washington, D.C. 20004
Tel: (202) 942-5000

Attorneys for Defendants Bristol-Myers Squibb Company, Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., and Sanofi-Synthelabo Inc.

Dated: July 5, 2013

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a copy of the foregoing has this day been filed using the CM/ECF system and it has been sent via electronic mail to counsel of record, Lisa Lanell Causey, at the following address: lcausey@salim-beasley.com

Dated: July 5, 2013

/s/ David L. Harris

David L. Harris